

# Under watch, copycat drug firms turn focus on quality

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Reuters

A SPATE of regulatory warnings for India's generic drug manufacturers will add a new emphasis on the quality of such medicines in an industry long dominated by the ability to deliver treatments as cheaply as possible, analysts say.

In the short term, that is expected to benefit larger global competitors, such as Teva Pharmaceutical Industries, Actavis and Mylan, which will be called upon to supply drugs no longer available from some of their rivals in India, they said.

Over the longer term, the trend will put a new premium on manufacturers who can demonstrate a strong quality record over time and limit supply disruptions, particularly as US drugstore chains and pharmaceutical wholesalers make deals that consolidate their buying on a larger scale than ever.

"When you talk to companies they will tell you that this was an industry that used to be about nothing but price. Now the ability to supply the market and have a reliable supply, to be in good favor with the FDA, that's starting to mean something to customers," said Gabelli analyst Kevin Kendra.

The biggest setback for India's \$14 billion a year generic drug industry came in January, when the FDA banned imports from all the Indian plants of Ranbaxy Laboratories, India's No 1 drugmaker by sales, over repeated production quality lapses.

While generic drugmakers based in the United States and elsewhere have also been cited by the US food and drug administration for quality control problems over the years, India's industry has come under fresh scrutiny recently as the agency steps up its in-



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spectations there.

On a smaller scale, the US health regulator banned medicines made at a Sun Pharmaceutical Industries plant at Karkhadi.

Sun has said that plant accounts for less than 1 percent of its sales.

Wockhardt and Dr Reddy's Laboratories have also run afoul of the FDA or been involved in recent major product recalls.

Some US doctors say the headlines have raised new concerns about the quality of the generic drug supply.

Pharmacy chains including CVS Caremark and Walgreen would not comment on whether they have altered their purchasing operations in any way.

Pharmacy benefits manager Express Scripts, one of the largest purchasers of generic drugs, would not single out India, but said it has taken notice of quality concerns on a company-by-company basis. We have increased our surveillance throughout the supply chain, said Express Scripts spokesman Brian Henry.

When products are temporarily removed from the US market, that has given

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some larger manufacturers the ability to take up pricing and pick up some share, said RBC Capital Markets analyst Randall Stanicky.

Jason Kolbert, an analyst with Maxim Group, sees Teva, with its vast geographic reach and huge product portfolio, as a direct beneficiary of Indian drug company setbacks. It sells, for example, a version of the antibiotics made at the Sun plant under FDA sanctions.

"These companies have to spend six months or a year fixing a manufacturing

quality control problem, so Teva is likely to pick up a little bit of growth because this is not their problem," Kolbert said.

Morningstar analyst Michael Waterhouse said purchasers would likely make a distinction between Ranbaxy, which has repeatedly been cited by the FDA for lapses, against its Indian peers that have had more sporadic problems, not unlike companies elsewhere around the globe.

"The FDA overall is trying to raise the bar because it's a brutal industry for a lot of these companies where the pricing pressure is so hefty," he said.

Wockhardt, Ranbaxy and Dr Reddy's did not respond to requests for comment.

Piyush Nahar, an analyst with Jefferies India Private, said Indian drugmakers have increased their investment in compliance and some are considering investing in US or European plants to overcome regulatory challenges. Waterhouse expects those efforts to pay off. Ultimately you would think standards would be raised in India and they would still remain a formidable opponent, he said.

*Regulatory,*